

REMARKS

The present reply is responsive to the Office Action dated September 24, 2009. Claims 1-16 are again presented for consideration in view of the following remarks. A petition for a one month extension of time accompanies this reply.

Several new grounds of rejection are presented in the pending Office Action. Specifically, claims 1-3, and 14-16 were rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,937,853 ("Strom") in view of U.S. Patent Publication No. 2002/0014239 ("Chalvignac") and U.S. Patent No. 3,961,627 ("Ernst"). Claims 4-6 were rejected under 35 U.S.C. § 103(a) as being obvious over Strom, Chalvignac and Ernst as applied to claim 1 on page two of the Office Action, and further in view of U.S. Patent No. 5,307,795 ("Whitwam"). Claims 7-10 were rejected under 35 U.S.C. § 103(a) as being obvious over Strom, Chalvignac and Ernst as applied to claim 1 and further in view of U.S. Patent No. 5,308,040 ("Torres"). Claims 10 and 12 were rejected under 35 U.S.C. § 103(a) as being obvious over Strom, Chalvignac and Ernst as applied to claim 1 and further in view of U.S. Patent No. 5,813,410 ("Levin"). Claim 11 was rejected under 35 U.S.C. § 103(a) as being obvious over Strom, Chalvignac, Ernst, and Levin as applied to claim 10 on page nine (9) of the Office Action, and further in view of U.S. Patent No. 6,102,038 ("DeVries"). Claim 13 was rejected under 35 U.S.C. § 103(a) as being obvious over Strom, Chalvignac, Ernst, and Levin as applied to claim 12 on page nine (9) of the Office Action, and further in view of U.S. Patent No. 5,735,267 ("Tobia"). Of these, claims 1, 12 and 14 are independent. Applicant respectfully traverses the rejections.

Turning first to claim 1, a discussion of Strom is provided below. As best understood, Strom describes a ventilator for respiratory treatments. In particular, this ventilator is able to automatically choose between a controlled ventilation mode, in which the ventilator is working according

to preset values, and a supported ventilation mode, in which the patient's breathing is spontaneous and supported by the ventilator. (See 1:26-53 and 2:15-18)

Notwithstanding this, it appears that several features of the breathing apparatus according to claim 1 are not described in *Strom*.

The ventilator described in *Strom* neither comprises "an inhalation valve disposed on the inhalation duct, the inhalation valve comprising means to allow the gas from the gas source to pass to make possible proportional operation", nor "an expiratory valve on the expiratory duct to help establish a positive expiratory pressure". In addition, *Strom*'s ventilator does not comprise "a comparator configured for transmitting an operating reference value of a gas related parameter to the pressurized respiratory gas source for the control of said gas source operation between or during the inhalation and expiratory phases, said comparator having a first input for one or more reference values of the gas related parameter, and a second input being connected to a switch configured for real time selective connection of the comparator with the pressure sensor or the flow rate sensor, allowing real time transmission of a pressure signal or flow rate signal, the position of said switch determining a barometric or volumetric mode of the apparatus."

The combination of a pressurized gas source, an inhalation valve capable of operating proportionally and a direct closed loop regulation, comprising several components such as a comparator and a switch, as set forth in claim 1, allows a control of the operation of the apparatus with great precision, in particular over wide ranges of flow. It also provides the ability of switching between barometric and volumetric modes in real time, even during the inhalation or expiratory phases. The advantages of this combination are clearly pointed out in the specification of the present patent

application. See, e.g., p.13, ll.3-28 and p.14, ll.1-7 of the application as filed. These technical features and their combination are not disclosed in *Strom*. By way of example, no inhalation and exhalation valves are described in the ventilator of *Strom*.

In addition, *Strom* describes a very general regulating unit (see FIG. 1, regulating unit (14)), which neither comprises a switch suitable for switching between barometric and volumetric modes in real time, even during the inhalation or expiratory phases, nor a comparator such as the one set forth in claim 1.

As shown in the description of the embodiments, the ventilator of *Strom* is designed for switching between supported ventilation and controlled ventilation modes only, whether these modes are pressure or flow controlled. The initial parameters, i.e. pressure or flow mode, are set by the operator, as suggested in *Strom* at 4:47-51.

The ventilator in *Strom* may in one embodiment switch from pressure regulated volume controlled mode to volume controlled mode, but only if the device is unable to calculate a proper airway impedance, not to adjust to patient ventilation requirements. (See 6:54-63)

In particular, the ventilator according to *Strom* is not able to switch in real time between barometric and volumetric modes, even during the inhalation or expiratory phases, and even during the implementation of a particular mode. In the claimed invention, this allows for example the implementation of a Volume Assured Pressure Support (VAPS) mode in real time. (See p.16, ll.4-19 of the application as filed.) *Strom* thus cannot achieve the advantages of the invention because it fails to disclose the particular combination of structural features according to claim 1.

Applicant respectfully submits that, notwithstanding the assertions set forth in the rejection, one of ordinary skill in the art would not be motivated to combine the ventilator of *Strom* with the devices described in *Chalvignac* and *Ernst*, which comprise completely different structures. There is no proper rationale why the ventilator of *Strom*, which does not comprise any inhalation and exhalation valves, could be combined with the ventilator teachings of *Chalvignac* and *Ernst*, which comprise inhalation and exhalation valves.

For instance, *Chalvignac* is directed to a ventilator apparatus comprising a proportional valve that is driven by a motor and a differential pressure sensor that is used to control the flow with the valve (ct. Figure 2). A constant pressure difference is maintained across the valve with the flow being proportional to the opening of the valve. The ventilator in *Chalvignac* relies on a closed loop system to control the valve (see ¶ [0078]), and on an open loop control of the pressure at the outlet of the gas source (see ¶ [0123]).

In contrast, the invention as set forth in claim 1 relies on a different configuration. An open loop system is used to control the inhalation valve, and a direct closed loop regulation, comprising several components such as a comparator and a switch, is used to control the pressurized gas source itself. No differential pressure sensor is used. Therefore, the applied combination of references cannot yield the present invention.

Turning to *Ernst*, this reference describes a ventilator comprising means for the regulation of the pressure or flow. However, this pressure or flow control is carried out on a control valve (4), and not on the source of respiration gas (2). See FIG. 1 of *Ernst*, where the source of respiration gas appears not to be controlled. The comparator (7) in *Ernst* does not send a reference value to the source of respiration gas, but

a control signal to the control valve (4) through a valve control (6) for modulating said control valve (4). (See *Ernst* 4:1-9 and FIG. 1). Therefore, the applied combination of references cannot yield the present invention.

Even one of ordinary skill in the art, though not properly motivated, had combined the three ventilators and other teachings of *Strom*, *Chalvignac* and *Ernst*, it would not result in the claimed invention, suitable for controlling the operation of the apparatus with great precision, in particular over a wide range of flow, and suitable for switching between barometric and volumetric modes in real time, even during the inhalation or expiratory phases.

In view of the above, applicant submits that there is no proper motivation to combine the references in the manner set forth in the rejection. Furthermore, even if it were possible to combine the teachings of *Strom*, *Chalvignac* and *Ernst* in the manner asserted in the rejection, they would not result in the invention of claim 1. Therefore, applicant respectfully requests that the rejection of independent claim 1 be withdrawn.

Claim 12 includes the structural features of claim 1. As discussed above, claim 1 is patentable over the applied combination of *Strom*, *Chalvignac* and *Ernst*. Applicant submits that *Levin* fails to overcome the deficiencies of that combination, and thus claim 12 is likewise patentable.

In addition, claim 12 describes the operation of a micro turbine and the closing of the expiratory valve based on the micro-turbine to regulate a positive expiratory pressure during the expiratory phases. The use of a micro turbine in combination with the expiratory valve is very advantageous. It does not generate unwanted side effects (e.g., vibrations, operating anomalies, etc.), and thus permits to dispense with the additional means (filters) that are usually positioned between the auxiliary pressure source and the expiratory valve.

Strom neither describes an expiratory valve nor a micro-turbine. *Chalvignac* does not disclose or suggest the use of a micro turbine, but instead describes a fan (see ¶ [0043]), which is a common auxiliary pressure source. *Ernst* does not teach or suggest the use of a micro turbine. It thus appears that none of the ventilators cited in the prior art describes the use of a micro-turbine in combination with an expiratory valve, in order to regulate a positive expiratory pressure during the expiratory phases.

Levin admittedly describes the use of a micro-turbine. However, *Levin's* micro-turbine is used in a very different technical domain, i.e., internal body pumps, and is not connected to any valve. In view of this, applicant submits that it would not have been obvious to one of ordinary skill in the art at the time the invention was made to have used the micro-turbine teachings of *Levin* with the combination of *Strom*, *Chalvignac* and *Ernst* as set forth in the rejection. In view of the above, applicant submits that claim 12 is patentable over *Strom*, *Chalvignac*, *Ernst* and *Levin*. Therefore, applicant respectively requests that the rejection of independent claim 12 be withdrawn.

Claim 14 includes the structural features of claim 1. As discussed above, claim 1 is patentable over the applied combination of *Strom*, *Chalvignac* and *Ernst*. The same arguments as for claim 1 apply to claim 14 as well. For at least this reason, applicant submits that claim 14 is patentable over this combination.

In addition, claim 14 describes the control of the gas source in a volumetric mode. In this process, the closed loop made by the flow rate sensor, the comparator, and the controlled pressurized gas source, allows the control of the pressurized gas source through an operating reference value (flow value in the volumetric mode) transmitted by the comparator to said pressurized gas source. Applicant submits that the applied combination does not disclose or otherwise suggest such

features. In view of the above, applicant submits that claim 14 is patentable over *Strom*, *Chalvignac*, and *Ernst*. Therefore, applicant respectively requests that the rejection of independent claim 14 be withdrawn.

Furthermore, claims 2-11, 13 and 15-16 depend from independent claims 1, 12 and 14, respectively. For at least the reasons presented above, applicant submits that the subject dependent claims are patentable and requests that the rejections of these claims be withdrawn.

As it is believed that all of the rejections set forth in the Office Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that she telephone applicant's attorney at (908) 654-5000 in order to overcome any additional objections which she might have. If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

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Respectfully submitted,

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